

Translation

PATENT COOPERATION TREATY

PCT/JP2003/014138



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 3118WO0P	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2003/014138	International filing date (day/month/year) 06 November 2003 (06.11.2003)	Priority date (day/month/year) 07 November 2002 (07.11.2002)
International Patent Classification (IPC) or national classification and IPC C07K 7/08, A61K 38/10, C07K 16/18, A61K 39/395		
Applicant TAKEDA PHARMACEUTICAL COMPANY LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 11 December 2003 (11.12.2003)	Date of completion of this report 22 October 2004 (22.10.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP2003/014138

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement under Article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. See Supplemental Box

because:

☒ the said international application, or the said claims Nos. 58, 60  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The inventions of claims 58 and 60 concern treatment of the human body by surgery or therapy.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. See Supplemental Box

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	1-5, 10, 12-15, 17, 19, 20, 22-24, 26, 27, 59, 61	YES
	Claims		NO
Inventive step (IS)	Claims	1-5, 10, 12-14, 17, 19, 20, 22-24, 26, 27, 59, 61	YES
	Claim	15	NO
Industrial applicability (IA)	Claims	1-5, 10, 12-15, 17, 19, 20, 22-24, 26, 27, 59, 61	YES
	Claims		NO

### 2. Citations and explanations

Based on the description in document 1 (Nature, 1981, Vol. 290, p. 457-465) cited in the international search report, the invention of claim 15 lacks an inventive step. Document 1 describes the human mitochondrial genome base sequence, and it describes the gene encoding cytochrome c oxidase subunit I that is included in the amino acid sequence identified as SEQ ID NO: 22 of this application (Figure 1). Persons skilled in the art can easily conceive of expressing this cytochrome c oxidase and obtaining antibodies thereto. This examination also finds that these antibodies include those that bind to the peptide comprising the amino acid sequence represented by SEQ ID NO: 22 of this application.

The inventions of claims 1-5, 10, 12-14, 17, 19, 20, 22-24, 26, 27, 59, and 61 are novel and involve an inventive step with respect to the documents cited in the international search report. Document 1 does not describe an association between cytochrome c oxidase and FPRL1, and persons skilled in the art cannot easily conceive of this matter.

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box III:

**Box III, Item 1**

Excepting claims 6-9, 11, 16, 18, 21, 25, 28-57, 58, and 60, and the parts of claims 12-14, 19, 22, 23, 26, 59, and 61 that cite claims 1-5.